

Message Text

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ORIGIN ABF-01

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DRAFTED BY A/BF/OAG:DLQUAID
APPROVED BY A/BF/OAG:JHSOUTHERLAND
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FM SECSTATE WASHDC
TO AMEMBASSY OTTAWA

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E.O. 11652: N/A.

TAGS: AGAO, ECSM

SUBJECT: GAO REVIEW: "NEW DRUG DEVELOPMENT AND APPROVAL
PROCESS".

1. DEPARTMENT HAS BEEN ADVISED BY GAO OF SUBJECT REVIEW
WHICH WAS INITIATED AT CONGRESSIONAL REQUEST.
2. GAO WOULD LIKE TO COMPARE THE REQUIREMENTS, POLICIES,
AND PRACTICES USED BY OTHER COUNTRIES TO REGULATE NEW DRUG
DEVELOPMENT TO DETERMINE WHETHER NEW DRUGS ARE INTRODUCED
MORE RAPIDLY THAN IN THE U.S.
3. IN THIS REVIEW, GAO IS INTERESTED IN OBTAINING INFO-
RMATION FROM KNOWLEDGEABLE FOREIGN GOVERNMENT AND BUSINESS
OFFICIALS AND ACADEMICIANS ON THE FOLLOWING MATTERS: (A)
THE LAWS, IMPLEMENTING REGULATIONS, AND OVERALL PHILOSOPHY
FOR REGULATING NEW DRUG APPROVALS; (B) PROCEDURES FOR
REVIEWING AND APPROVING PRECLINICAL AND CLINICAL TEST DATA
AND NEW DRUG APPLICATIONS; (C) METHODS USED TO INSURE
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TIMELY REVIEW OF SUBMITTED DATA; (D) STATISTICAL DATA ON
THE SIZE OF THE REVIEW GROUPS USED IN OTHER COUNTRIES,
THEIR WORKLOAD, AND THE TIME REQUIRED TO TEST AND APPROVE
NEW DRUGS. FOLLOWING A PILOT TEST OF THEIR REVIEW APPROACH
IN CANADA, GAO PLANS VISITS TO EUROPE AND THE FAR EAST.

4. THE FOLLOWING CANADIAN OFFICIALS WERE IDENTIFIED TO

GAO BY THE CANADIAN EMBASSY IN WASHINGTON. IN ADDITION TO THOSE NAMED, GAO WOULD APPRECIATE EMBASSY ASSISTANCE IN ARRANGING AN INTERVIEW WITH AN OFFICIAL OF THE BUREAU OF DRUG SURVEILLANCE.

A) DR. A.B. MORRISON, ASSISTANT DEPUTY MINISTER, HEALTH PROTECTION BRANCH; (B) DR. R.C.B. GRAHAM, ASSISTANT DIRECTOR, BUREAU OF DRUGS; (C) DR. IAN HENDERSON, CANADIAN MEDICAL ASSOCIATION. ALL OF THE ABOVE ARE LOCATED IN OTTAWA.

5. THIS REVIEW IS BEING CARRIED OUT BY STAFF FROM THE GAO DETROIT REGIONAL OFFICE. THEY PLAN TO BE IN OTTAWA FROM APRIL 4 THRU 7. NAMES OF AUDITORS AND REQUEST FOR ASSISTANCE IN ARRANGING ACCOMMODATIONS WILL FOLLOW BY SEPTEL.

6. GAO TEAM WOULD BE PLEASED TO BRIEF THE AMBASSADOR ON THE RESULTS OF THIS VISIT IF DESIRED. PLEASE ADVISE.

7. DEPARTMENT WISHES TO COOPERATE WITH THE GAO IN ACCORDANCE WITH THE GUIDELINES IN 4 FAM 930-934. GAO IS AWARE THAT CONTACTS WITH HOST GOVERNMENT OFFICIALS ARE AT THE DISCRETION OF THE AMBASSADOR, TO BE ARRANGED FOR BY THE EMBASSY, AND AN EMBOFF TO ACCOMPANY, IF FEASIBLE. CHRISTOPHER

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